



NEWS RELEASE

OFFICE OF THE UNITED STATES ATTORNEY
WESTERN DISTRICT OF MISSOURI

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Audio comments from U.S. Attorney Todd Graves, in MP3 format, and photos from today's press conference are available to download from the district's Web site at www.usdoj.gov/usao/mow

PHARMACEUTICAL DISTRIBUTORS INDICTED FOR \$42 MILLION LIPITOR SMUGGLING, COUNTERFEITING

KANSAS CITY, Mo. – Todd P. Graves, United States Attorney for the Western District of Missouri, announced that three businesses and 11 individuals involved in the pharmaceutical wholesale distribution industry were indicted by a federal grand jury today for participating in a \$42 million dollar conspiracy to sell counterfeit, illegally imported and misbranded Lipitor and other drugs, and for participating in a conspiracy to sell stolen drugs.

Douglas C. Albers, 53, of Leawood, Kan., **Albers Medical Distributors, Inc.**, a Missouri corporation owned and operated by **Albers, Paul Louis Kriger**, 48, of Thousand Oaks, Calif., **Michael Allyn Carlow**, 52, of Fort Lauderdale, Fla., **Richard K. Rounsborg**, 47, of Kearney, Neb., **Med-Pro, Inc.**, a Nebraska corporation owned and operated by **Rounsborg, Christopher W. Lamoreaux**, 35, currently an inmate in federal custody, **Noah Salcedo-Smith**, 34, of San Fernando, Calif., **H.D. Smith Wholesale Drug Company**, an Illinois corporation, **Frank Anthony Ianeillo**, 61, of Stillwater, Penn., **Gary Wayne Smith**, 36, of Mobile, Ala., **Albert David Nassar**, 50, of New York, N.Y., **Salvatore A. Esposito**, 47, of Staten Island, N.Y., and **Alexander Anthony Nassar**, 41, of Miami, Fla., were charged in a 57-count indictment returned by a federal grand jury in Kansas City.

“Today’s indictment has significant national public health ramifications,” Graves said. “Tens of millions of dollars in counterfeit, illegally imported and stolen drugs were bought and sold and, ultimately, prescribed to consumers. Today’s indictment shines a light on a little-known aspect of marketing prescription drugs, a secondary market that can be vulnerable to unscrupulous wholesalers who introduce counterfeit, stolen and illegally diverted drugs into the

national distribution system.”

Graves explained that today’s indictment charges businesses and individuals involved in the secondary wholesale market. Prescription drug manufacturers use a multi-tier system of wholesalers to distribute prescription drugs and pharmaceutical products in the United States. A few large companies with publicly traded stock occupy the top tier of the distribution system, purchasing drugs in large volumes directly from a drug manufacturer. In turn, these top-tier companies sell to several large regional wholesalers. Below the regional wholesalers are the secondary wholesalers, who buy and sell drugs to and from each other and also sell drugs to hospitals, clinics, doctors, and pharmacies.

This secondary wholesale market, Graves added, is characterized by aggressive trading in which the wholesalers attempt to buy low and sell high. “This isn’t illegal,” Graves said, “but it creates opportunities for unscrupulous wholesalers to illegally exploit the market by resorting to fraud and misrepresentation when buying or selling a drug.”

Today’s indictment is the culmination of an investigation that began in 2002, Graves said. In the course of this investigation, **Albers** – at the urging of the Food and Drug Administration – initiated a recall of more than 18 million Lipitor tablets, which Graves described as “perhaps the largest recall in the history of criminal investigations of counterfeit medications.”

Lester Crawford, commissioner of the Food and Drug Administration, underscored the national significance of today’s indictment. “This case demonstrates that the FDA will take the necessary steps to protect the drug supply from those who would profit from fraudulent schemes to sell pharmaceuticals of unknown safety and efficacy to the American public,” Crawford said.

Background information regarding the defendants, as well as others who have been charged in separate but related cases, is contained in the indictment.

Counterfeit, Illegally Diverted Lipitor

Count One of the federal indictment alleges that **Albers, Albers Medical Distributors, Kriger, Carlow, Salcedo-Smith, Lamoreaux, Rounsborg, Med-Pro, H.D. Smith Wholesale Drug Company, and Alexander Nassar** participated in a conspiracy to purchase and sell counterfeit, misbranded, and illegally imported drugs from February 2002 until at least April 2003. Co-conspirators, with the intent to defraud and mislead, allegedly caused the manufacture, importation, labeling, and repackaging of certain drugs, caused the misbranding and counterfeiting of certain drugs, and sold certain misbranded and counterfeited drugs.

According to the indictment, this was a two-pronged conspiracy: First, co-conspirators purchased genuine Lipitor and Celebrex intended for distribution in South America and illegally imported it into the United States. Graves explained that this is known as diversion.

Second, co-conspirators allegedly bought chemicals and equipment – including punches and dies purchased from a St. Louis, Mo.-area company and counterfeit drug labels purchased

from a Miami, Fla.-area company – which they shipped to Costa Rica to manufacture counterfeit Lipitor, which they then illegally imported into the United States. Co-conspirators commingled the illegally imported Lipitor with the counterfeit Lipitor, Graves added, and sold it in the United States.

This was accomplished by, among other things, making false and fraudulent representations to the U.S. Customs Service. Co-conspirators also created false pedigrees for the drugs. Graves explained that, under federal law, wholesalers must furnish their buyers with a written statement identifying the persons and entities from whom the drug was purchased. Within the wholesale drug industry, this written statement is referred to as a pedigree.

During the 11-month time period from May 8, 2002, to April 4, 2003, **Albers, Albers Medical Distributors**, and **Kriger** allegedly paid **G & K Pharma** more than \$42 million to purchase drugs from **Carlow**. **Albers**, a Missouri-licensed pharmacist, owned and operated **Albers Medical Distributors**, a wholesale pharmacy at 4400 Broadway in Kansas City, Mo. **Kriger** owned and operated OTS Sales, Inc., which he used to buy and sell drugs in the secondary wholesale drug market on behalf of **Albers** and **Albers Medical Distributors**. **Carlow** owned and operated **G&K Pharma**, a company that was used to buy and sell drugs in the secondary wholesale drug market.

Between Nov. 14, 2002, and March 20, 2003, **Albers Medical** allegedly made a dozen shipments of counterfeit and illegally imported Lipitor tablets to **Rounsborg** and **Med-Pro**. **Rounsborg** was the owner and president of **Med-Pro**, a company in Lexington, Neb., that engaged in the business of repackaging, distributing, and selling pharmaceutical products and drugs. **Albers Medical** paid \$173,399 to **Rounsborg** and **Med-Pro** to repackage the counterfeit and illegally imported Lipitor tablets with the intent to misbrand them by concealing their true origin and prevent their detection.

In April 2003, **Rounsborg** allegedly attempted to prevent federal law enforcement agents from learning about the conspiracy when he falsely stated to those agents that all the purported Lipitor received by **Med-Pro** had arrived in bottles with labeling prepared by the Pfizer, the lawful manufacturer. In reality, the indictment says, **Rounsborg** knew that much of the purported Lipitor had arrived in containers with a generic black and white label which he knew had not been prepared by the lawful manufacturer, and which he knew was an indication that the purported Lipitor was not approved for sale or distribution in the United States.

In June 2002 and in the early months of 2003, Diana Coelyn, acting in her capacity as an agent of **H.D. Smith Wholesale Drug Company**, an Illinois company engaged in the business of buying and selling drugs in the secondary wholesale drug market, allegedly had several telephone conversations with co-conspirators related to drugs that were being repackaged by **Med-Pro**. Coelyn, who was charged in a separate but related case, allegedly spoke with **Rounsborg** to discuss his receipt of bulk Lipitor in bottles with black and white printed labels that were dirty and smeared, as well as another shipment of Lipitor in bottles that appeared originally to have come from blister packs. In subsequent conversations that Coelyn had with **Kriger** and **Albers**, the decision was made to continue repackaging the suspect Lipitor despite their concerns that the

product had been illegally diverted, the indictment alleges.

Between July 2002 and March 2003, **Albers, Albers Medical Distributors** and **Kriger** allegedly paid more than \$400,000 in secret commissions and kickbacks to Coelyn.

In January 2003, **Kriger, Carlow** and **Salcedo-Smith** (who worked for **Kriger** and was involved in the day-to-day operation of OTS Sales) allegedly caused the issuance of pedigree papers that falsely stated the source and origin of the counterfeit, illegally imported, and misbranded Lipitor being sold and distributed by the members of the conspiracy.

Between February and June 2003, **Alexander Nassar**, who operated New Horizons LLC, a company used to buy and sell drugs in the secondary wholesale drug market, allegedly caused the issuance of pedigree papers that falsely stated the source and origin of the counterfeit, illegally imported, and misbranded Lipitor being sold and distributed by the members of the conspiracy.

Counts Thirty-Six through Thirty-Nine of the federal indictment allege specific instances in which co-conspirators sold counterfeit Lipitor that had been commingled with illegally imported Lipitor

Counts Forty-Five through Fifty-Three of the federal indictment allege specific instances in which co-defendants introduced an unapproved new drug into interstate commerce. Lipitor was a new drug that must be mixed and packaged in conformity with the FDA-approved New Drug Application (used to approve the use of a new drug in the United States). Each of the sales alleged in these counts of the indictment involve counterfeit Lipitor tablets that had been commingled with illegally imported Lipitor that originally had been packaged at a facility outside the United States and not intended or approved for sale in the United States.

Illegally Diverted Celebrex

Count One of the federal indictment also alleges that, during June and July 2002, **Rounsborg** and **Med-Pro** received a shipment containing 200 mg. Celebrex capsules that were not approved for sale or distribution in the United States and that had been illegally imported into the United States by other members of the conspiracy. The inserts accompanying the Celebrex tablets, the indictment says, were written in Portuguese. **Rounsborg** and **Med-Pro** repackaged the illegally imported Celebrex capsules with the intent to misbrand them by removing the Portuguese inserts and thereby conceal the true origin of the illegally imported capsules and prevent their detection.

According to the indictment, **Albers Medical Distributors** paid **Rounsborg** and **Med-Pro** \$12,515 for repackaging the illegally imported Celebrex. The Celebrex was then shipped to locations outside the state of Nebraska.

Other Illegally Diverted Drugs

Count One of the federal indictment also alleges that in November 2002, **Lamorequx**, president and CEO of NuCare Pharmaceuticals, Inc., a California-based company engaged in the business of repackaging pharmaceutical drugs and products, agreed with **Albers, Albers Medical Distributors** and **Kruger** to remove the drug Coumadin from blister packages marked “for hospital use only” and repackage the drugs in bulk plastic bottles that would disguise and conceal the fact that the Coumadin was “for hospital use only.”

Between November 2002 and March 2003, **Lamorequx** allegedly agreed with **Albers, Albers Medical Distributors** and **Kruger** to repackage purported Bextra and Lipitor.

On two occasions in February and March 2003, **Albers, Albers Medical Distributors** and **Kruger** allegedly paid secret commissions and kickbacks to **Lamoreaux** totaling more than \$115,000.

Stolen Drugs

Count Two of the federal indictment alleges that **Albers, Albers Medical Distributors, Kruger, Carlow, Salcedo-Smith, Ianeillo, Smith, Albert Nassar, Esposito** and **Alexander Nassar** participated in a conspiracy to buy, sell and traffic in stolen drugs from December 2001 to April 2003.

The federal indictment alleges that co-conspirators purchased and sold among themselves drugs that they knew were stolen, that they created false pedigrees to conceal the fact that the drugs were stolen, and that they sold the stolen drugs in interstate commerce, knowing that consumers ultimately would purchase the stolen drugs.

According to the federal indictment, pharmaceutical drugs manufactured by Glaxo-Smith (Flonase, Imitrex, Advair and Flovent) were stolen from a location in North Carolina in December 2001 and taken to a warehouse in the Miami area, where they were inventoried by **Alexander Nassar**. Julio Cesar Cruz, who is charged in a separate but related case, faxed information about the stolen Glaxo drugs to **Albert Nassar. Esposito** and **Albert Nassar** allegedly purchased the stolen drugs and sold them to **Smith. Smith** then allegedly sold the stolen Glaxo drugs to **Ianeillo**, who allegedly sold them to **Kruger, Salcedo-Smith, Albers** and **Albers Medical Distributors**.

Albert Nassar and **Esposito** operated Worldwide Pharmaceuticals, a company used to buy and sell drugs in the secondary wholesale drug market. **Smith** operated Omega Pharmaceuticals, a company used to buy and sell drugs in the secondary wholesale drug market. **Ianeillo** operated Welcome Rx, a company used to buy and sell drugs in the secondary wholesale drug market.

Albers, doing business as **Albers Medical Distributors**, purchased the stolen Glaxo drugs for \$3,319,733, the indictment alleges. **Albers** then allegedly sold the stolen Glaxo drugs to various wholesale distributors.

According to the federal indictment, pharmaceutical drugs manufactured by Roche (Soriatane and Accutane) were stolen from a location in Florida in June 2002. Cruz contacted **Kriger** to see if **Kriger** wanted to purchase the stolen Roche drugs on behalf of **Albers Medical Distributors**. During this contact, the indictment alleges, Cruz told **Kriger** that the drugs were stolen. **Kriger** allegedly agreed to purchase the Roche drugs, knowing that they were stolen and that Cruz could not produce a legitimate pedigree for them.

Carlow allegedly agreed with **Kriger** to use **G&K Pharma** as a front to purchase the stolen Roche drugs from Cruz, and then use **G&K Pharma** to resell the stolen Roche drugs to **Albers Medical Distributors**. On June 26, 2002, **Albers** and **Albers Medical Distributors** allegedly wire transferred \$1,556,214 to **G&K Pharma** in payment for the stolen Roche drugs, which **Albers** sold to various wholesale distributors.

Counts Three through Nine of the federal indictment allege specific instances in which stolen Glaxo and Roche drugs were sold.

Counterfeit Serostim

Counts Ten through Fifteen of the federal indictment allege specific instances in which **Albers**, **Albers Medical Distributors** and **Kriger** sold counterfeit Serostim to various wholesale distributors from Sept. 7 to Nov. 15, 2000.

Serostim, Graves explained, is an injectable human growth hormone manufactured by Serono, Inc., for the treatment of cachexia, including AIDS-related wasting.

Counts Sixteen through Twenty-One of the federal indictment allege that **Albers**, **Albers Medical Distributors** and **Kriger** introduced misbranded Serostim into interstate commerce. The drugs labeled as Serostim allegedly bore a lot number or an expiration date that was false.

Counterfeit Neupogen

Counts Twenty-Two through Twenty-Seven of the federal indictment allege specific instances in which **Albers**, **Albers Medical Distributors** and **Kriger** sold counterfeit Neupogen to various wholesale distributors from April 5 to Sept. 25, 2001.

Neupogen, Graves explained, is an injectable human granulocyte colony stimulating factor used to stimulate the production of white blood cells in order to decrease the incidence of infections in persons with lowered immune systems, such as cancer patients receiving chemotherapy.

Counts Twenty-Eight through Thirty-Three of the federal indictment allege that **Albers**, **Albers Medical Distributors** and **Kriger** introduced misbranded Neupogen into interstate commerce. The drugs labeled as Neupogen allegedly bore a lot number or an expiration date that was false.

Counterfeit Procrit

Counts Thirty-Four and Thirty-Five of the federal indictment allege that **Albers, Albers Medical Distributors** and **Kruger** sold counterfeit Procrit in March 2003.

Procrit, Graves explained, is an injectable drug used in the treatment of anemia in patients with chronic renal failure and AIDS.

Graves cautioned that the charges contained in the indictment are simply accusations, and not evidence of guilt. Evidence supporting the charges must be presented to a federal trial jury, whose duty is to determine guilt or innocence.

This case is being prosecuted by Senior Litigation Counsel Gene Porter. It was investigated by the Office of Criminal Investigations, U.S. Food and Drug Administration.

This news release, as well as additional information about the office of the United States Attorney for the Western District of Missouri, is available on-line at
www.usdoj.gov/usao/mow